(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 20 December 2001 (20.12.2001)

PCT

English

(10) International Publication Number WO 01/95802 A1

(51) International Patent Classification7: A61B 5/113, 5/00

(21) International Application Number: PCT/US01/19055

(22) International Filing Date: 14 June 2001 (14.06.2001)

(25) Filing Language:

(26) Publication Language: English

(30) Priority Data:

00112681.2 15 June 2000 (15.06.2000) EP 00112680.4 15 June 2000 (15.06.2000)

(71) Applicant (for all designated States except US): THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors; and

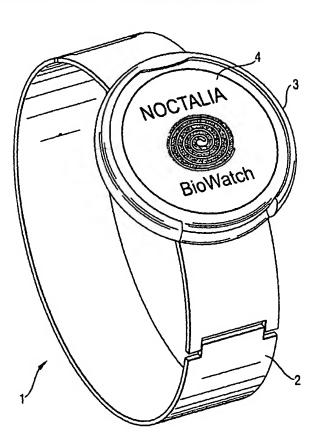
(75) Inventors/Applicants (for US only): BOSWELL, Emily, Charlotte [GB/GB]; 45 Harvesters Close, Isleworth, Middlesex TW7 7PP (GB). EWART, Keith [GB/GB]; 127 Harefield Road, Uxbridge UB8 1PN (GB). DIJK, Derk-Jan [NL/GB]; 9 West Meads, Guildford GU2 7ST (GB).

(74) Common Representative: THE PROCTER & GAM-BLE COMPANY; c/o T., Reed, David, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: BODY ACTIVITY DETECTION AND PROCESSING



(57) Abstract: A method for monitoring body activity comprises the steps of: receiving actimetry data from a sensor (11) for measuring body activity, analysing (17) the data to provide advisory information and displaying the advisory information (4).

WO 01/95802 A1



(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BODY ACTIVITY DETECTION AND PROCESSING

This invention relates to the detection of body activity, such as sleep patterns, and the analysis of data related to such functions for provision to a user.

In recent years there has been much study of body functions, such as sleep activity, and associated analysis of the relevance of such functions to the general health of the body and the body's need for appropriate body functions (such as sleep patterns) to occur on a regular basis for adequate periods of time. As part of this research numerous devices have been proposed to assist in such measurement and analysis.

For example, WO-A-9714354 discloses a device and corresponding method which collects data for analysing sleep disturbances so that such data can be interpreted by a specialist at a future date.

However, this type of device requires operation by a highly skilled user and provides analysis which is difficult to interpret by anybody other than a specialist, as well as being expensive and sometimes unreliable. Furthermore, it is unable to provide a detailed history over an extended time period for an individual.

Other systems are uncomfortable, cannot be worn for extended periods and/or cannot be worn without restricting body movement.

According to the present invention there is provided a method for monitoring body activity, the method comprising the steps of:

receiving actimetry data from a sensor measuring body activity;

analysing the actimetry data to provide advisory information, wherein the analysing step comprises the steps of:

determining parameters based on the actimetry data; and

combining these parameters to generate advisory information including a measure of the quality of the activity according to the following relationship:

$$AQI = C + \sum_{i=1}^{n} C_i P_i$$

where AQI is the "activity quality index", n is an integer greater than 1, C_I is a set of constants and P_I is the set of parameters, the parameters being at least one from the group of activity duration, activity efficiency, activity latency, activity bouts, number of activity interruptions and mean activity score; and outputting the advisory information.

The body activity being monitored may be sleep, and/or waking activity.

The data, including temporal information, may be stored prior to the analysis step. Both actimetry information and temporal information may be used in the analysing step.

The advisory information may include an indication of the quality of the activity, such as whether or not the duration of the activity is sufficient, an indication as to whether the total amount of the activity over an extended period is acceptable, as well as other data related to other long term body activity, for example. The device can be configured to detect activity during the day. The body activity that is measured can, as well as being actual time slept, be the number of awakenings, an indication as to how intermittent the sleep was, time taken before sleep, the number of and length of sleep interruptions, sleep proficiency, the number minutes immobile/moving, etc. A selection or all of this information can be provided to

identify the least and most active times during the day. The advisory information may include a comparison of the data with peer group data, statistical analysis, history data and solution/product choice to provide an improvement in activity quality or duration.

The data received may be collected by one or more additional sensors to also measure body pulse rate variability, blood pressure variability or other body activities such as eyelid movement or respiration. In this case, sleep phases such as REM, slow light sleep, slow deep sleep, or paradoxical sleep may be monitored.

Additional data may be provided to the analysing step by a human operator.

The invention is described for use in monitoring sleep patterns, however, it may also be of use in monitoring alternative body activities. For example monitoring daily activity levels to indicate whether the user is achieving sufficient activity in a fitness regime, whilst on a diet, during recuperation or, when bed rest is necessary, the level of activity of a patient determines whether bed sores will be prevented. A further example may be to study the activity of children who suffer attention deficit syndrome. There are many other scenarios where the standard method could be used to monitor the activity of people or even pets.

If further sensors were introduced such as a heart rate sensor the method could be used to monitor the heart rate either during sleep, to determine the different phases of sleep or during sports activities to monitor the heart rate without the need for any cumbersome chest band. The method could also be used to determine how stressed somebody was and potentially warn of impending heart problems.

Introduction of a global positioning system in combination with the actimetry sensor would allow the method to be used to track the whereabouts and activity of

children, old people (particularly Alzheimer's patients) or perhaps criminals on probation. If the actimetry sensor were used in combination with a clock, the method could be used to help controlling jet lag by recommending the best sleeping habits to cope with a particular difference in time zone.

The components of the "activity quality index" (AQI) may be defined by n=12, the twelve parameters, P_I, may be respectively time in bed, sleep end time, actual sleep time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time and wake movement RMS. The constant C may be 52.42 and the constants C_I associated with each of the parameters P_I respectively may be -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112 and 0.001238.

A computer readable storage medium comprising instructions for performing the steps of the method may be provided according to the present invention.

A computer configured to perform the steps of the method may be provided according to the present invention.

One example of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a schematic, perspective view of components of a system which may provide data for a method of the present invention;

Figure 2 is a schematic diagram showing some of the functionality of the system of Figure 1;

Figure 3 to 6 are diagrams showing possible displays from the system of Figure 1;

Figure 7 is a schematic diagram of the internal components of the system of Figure 1; and

Referring to Figure 1, a system which may be used to collect data for the method of the present invention has, in this example, a monitoring device 1 configured as a wrist watch-style device, with a strap 2 and a component-containing housing 3. On the outer surface of the housing 3 is an optional display 4, which in this case is a liquid crystal display.

The system may further comprise a receiving device 5, often referred to as a docking station which, in use, can receive the monitoring device 1 and connect with it to retrieve data from the device 1. The receiving device 5 may be, in turn, connected to an analysing device 6, which in this case is an appropriately configured PC, although it could be a dedicated piece of hardware. In this case the receiving device 5 and analysing device 6 are shown as separate components, although this may not necessarily be the case. The analysing device 6 has its own display 7, and may optionally have the ability to connect to a remote terminal (not shown) via an internet link or some other form of communication device.

Referring to Figure 7, the device 1 of Figure 1 has a number of internal components. The device 1 is powered by a battery 10 (or another power supply) which supplies power to the other components of the device 1. An actimetry sensor 11 detects motion in the device 1 and hence motion in the body to which the device 1 is attached in use. The data from the actimetry sensor 11 is passed to a memory 12. A clock 13 also provides temporal data to the memory 12 and to the actimetry sensor 11 if necessary, as well as optionally to the display 4. In addition to the

actimetry sensor 11, the device 1 may further comprise additional sensors 15, 16, which may detect blood pressure, pulse rate variation etc. Data from these additional optional sensors 15, 16 may also be forwarded to the memory 12.

As described above, the monitoring device 1 has the ability to send data to the receiving means 5 via a transmitter 20, in this case through a fixed connection between the two when the user places the monitoring device 1 in the receiving device 5. As an alternative, the monitoring device 4 may transmit and/or receive data from the receiving means 5 via a wireless link such as an infra red link. In this latter case, data from the memory 12 can be requested from analysing means 6, either on a regulated intermittent, continuous, or on a user-requested basis.

A wide variety of different forms of analysis may be performed by the analysing means 6.

Examples of the types of analysis that may be performed will now be described with reference to Figures 2 to 6.

The actimetry sensor 11 may provide information in relation to sleep duration and the type of sleep to the analysing means 6. This information can be analysed by the analysing means 6 to provide information to the display 4, simply in terms of the total number of hours of sleep obtained, although it may provide additional information in relation to the quality of the sleep and the expected value of that sleep in terms of an "energy bank". By using data stored in the memory 12 or as the base unit in an additional memory (not shown) over a number of days, weeks or months, the analysing means 6 may also provide information indicative of accumulated sleep deficit or sleep excess. As mentioned above, the data can be provided to a user as and when requested, and is arranged to be provided in a very simple format so that it does not need complex interpretation.

The analysing means 6 may employ a scale, for example the Stanford sleep scale, in order to score the monitored, sleep and provide relevant information to the user and to some subject we input from the user. The scale defines different levels of sleepiness as follows;

- 1 feeling active, vital, alert, wide awake.
- 2 functioning at a high level, not at peak.
- 3 relaxed, not full alertness, responsive.
- 4 a little soggy, not at peak, let down.
- 5 tired, losing interest, slowed down.
- 6 drowsy, prefer to be lying down.
- 7 almost in a reverie, hard to stay awake.

This scale can be shown to a user so that the user can input an indication of how tired they consider themselves to be. For example, the user could be prompted to input an indication as to how they feel when they wake up, with an indication as to the reasons for their feelings being provided by the analysing means 6 from the data collected.

In another example, such an input could be employed during the initial weeks of employing the device to help the system determine whether or not the user is sleeping for the right amount of time for them. For example, on the first day of wearing the device the system may prompt the user to indicate how much sleep they consider they need. It could then provide information regarding the average sleep requirement for someone of their age and sex. However, as the requirements vary from user to user, the system can then monitor sleep over a given period and prompt the user for feedback, not only at the time during the day in order to form a sleep diary in the memory of the system. The system may then be configured to adapt the indications that it gives the user, based upon the feedback and wake the

user at the appropriate time, and then employing a sleep bank once the user's particular requirements have been determined.

The device 1 may have an alarm 18, which can be used simply to wake the user, in the manner of a normal wrist watch alarm, although it may be activated by the analysing means 6 (in conjunction with a heart rate monitor), when it is detected that an appropriate type of sleep is occurring to ensure gentle waking of the user.

If additional sensors 15, 16 are provided then additional analysis can be performed dependent upon the type of sensor to provide additional or more detailed and accurate information to the user. If the sensors detect parameters external to the body, such as light, location, sound, air temperature, humidity, barometric pressure, then this information may be compared with information relating to body activity in order to adjust their information. If the sensors determine additional body activity, and detect one or more of muscle tonus, skin temperature, galvanic skin response, etc then additional analysis of the quality of the sleep may be provided.

As a further example, if a blood pressure sensor is employed then additional indications related to general levels of health and activity not specifically related to sleep alone can be provided by the analysing means. If a pulse rate variability detector is employed then this can assist in determining the type of sleep detected, and can provide further information in relation to whether an acceptable level of aerobic exercise has been performed within the allotted time period, whether it be a day, a week or a month.

If the system provides some form of "sleep bank" indication over a period of time (generally 7 days), then the sleep bank may calculate the information to be provided to the user by including a formula such as:

sleep bank (i) = sleep bank (i-1) + (sleep (i) - need) where "sleep bank" is the accumulated sleep balance on day i, "sleep" is sleep achieved on the night before day i and "need" is sleep needed (which can change dependent upon other measured parameters, or upon stored data, or can be set manually).

In the case when the analysing means 6 has a line to a remote station, more complex analysis can be performed and it may be possible for the analysing means 6 also to request and obtain data from a human specialist or an extended database so that additional information can be provided to the user.

In addition, the system enables the storage of long term data in such a manner that it can be tracked to give a high quality user history for treatment, as well as for identifying long term trends that would not come to light in a short term analysis.

In a further example the additional analysing means 6 may not be provided. In this case, the receiving device (or docking station) 5 may be configured to perform the analysis procedure, whilst the level of analysis would necessarily be less comprehensive than the analysing means 6, due to the reduced processing capacity, the unit still provides a useful function to the user. The docking station 5, illustrated in figure 5, is provided with a display 31 and two control knobs 33,34 to enable the user to select and display information from the analyses performed by the unit 5. Recess 32 is provided to locate the sensor device 1 in the correct relative position to assist in downloading the information stored within it.

In use, the sensor device 1 will be initialised in the docking station 5 prior to use (i.e. before bed time). When the user wishes to retire the sensor device 1 will be removed from the docking station 5 and placed on the wrist. The docking station 5 comprises its own internal clocking mechanism and hence removing the sensor device 1 from the recess 32 on the docking station 5 will automatically provide "bed

time" information. Similarly "wake time" will automatically be recorded when the sensor device 1 is replaced into the recess 32 of the docking station 5 the following morning. This facility reduces the need for the user to keep a paper "sleep diary" and consequently makes the system easier to use.

Alternatively the monitoring device 1 may not comprise a storage facility 12. In this case the data acquired by the actimetry sensor would be transmitted directly to the docking station 5 for storage in real time.

Provision of a more sophisticated docking station 5, as seen in this example, removes the need for a user to have a computer available to perform the analyses. However the level of analysis achieved, as described above, may be less comprehensive. The docking station 5 is a highly portable unit that may easily be taken periodically, typically fortnightly, to an expert sleep analyst for further interrogation and more detailed advice. A download facility is provided within the docking station 5 to further assist in this interrogation process.

The sleep expert will provide a more detailed analysis of the user's sleep patterns. For example, in order to provide a measure of sleep quality, as described above, a parameter "Sleep Quality Index" (SQI) may be provided. The algorithm for this parameter, SQI, is based upon many of the parameters which are easily monitored, or derived, by the invention. The algorithm is of the form

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

This algorithm uses twelve parameters and their associated constants (i.e. n=12). The parameters are

Time in bed

Sleep efficiency

Mean wake bout time

Sleep end	Sleep latency	Mean activity score
Actual sleep time	Sleep bouts	Mean score inactive
Actual sleep (%)	Wake bouts	Wake movement RMS

Corresponding constants may be defined by the values 52.42, -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112, 0.001238. Alternatively, this algorithm can be tailored to represent an individual user to achieve results of greater accuracy.

Solution of this algorithm can be intensive in terms of processing requirements. Where the processing capacity is not extensive, as in the example where the docking station 5 is not supplemented by the analysing device 6, a simpler formulation is implemented. In this case, a value for quality of sleep is estimated by the user and this value is modified, based on four of the monitored/derived parameters (those marked *) above. This basic interpretation of sleep quality gives a lower predictive accuracy, nevertheless it provides a useful gauge, on a day to day basis, for the user of the system.

CLAIMS

 A method for monitoring body activity, the method comprising the steps of: receiving actimetry data from a sensor measuring body activity;

analysing the actimetry data to provide advisory information, wherein the analysing step comprises the steps of:

determining parameters based on the actimetry data; and

combining these parameters to generate advisory information including a measure of the quality of the activity according to the following relationship:

$$AQI = C + \sum_{i=1}^{n} C_i P_i$$

where AQI is the "activity quality index", n is an integer greater than 1, C_i is a set of constants and P_i is the set of parameters, the parameters being at least one from the group of activity duration, activity efficiency, activity latency, activity bouts, number of activity interruptions and mean activity score; and

outputting the advisory information.

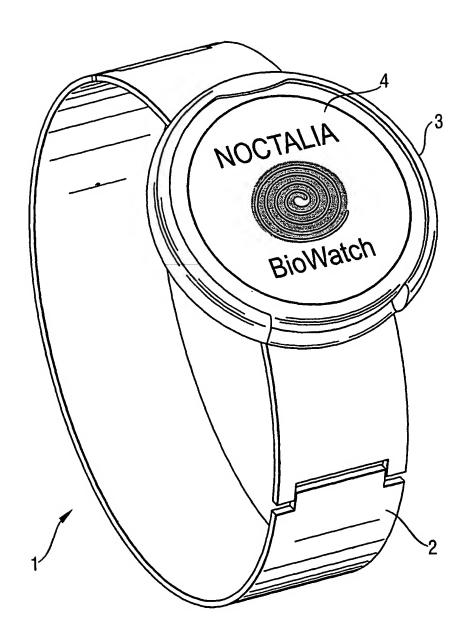
- 2. A method according to claim 1, wherein the body activity being monitored is sleep.
- 3. A method according to claim 1 or claim 2, further comprising the step of storing the activity data and temporal information prior to the analysis step.
- 4. A method according to claim 3, wherein the analysing step is based upon both actimetry information and temporal information.
- 5. A method according to any of the preceding claims, wherein the advisory information includes a further indication of the quality of the activity, including at least one of whether or not the duration of the activity is sufficient, an indication as

to whether the total amount of the activity over an extended period is acceptable, or other data related to other long term body activity.

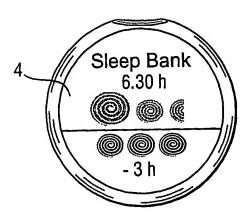
- 6. A method according to any preceding claim, wherein the advisory information further includes at least one of comparative data to peer group data, statistical analysis, history data and solution/product choice to provide an improvement in activity quality or duration.
- 7. A method according to any preceding claim, wherein the actimetry data further comprises data from at least one additional sensor measuring at least one of body pulse rate variability, and/or blood pressure.
- 8. A method according to claim 7, wherein sleep phases of REM, slow light sleep, slow deep sleep, or paradoxical sleep are monitored.
- 9. A method according to any preceding claim, wherein additional data is provided to the analysing step by a human operator.
- 10. A method according to any preceding claim, wherein the data in the receiving step further comprises data relating to the environment in which the body is placed which is detected by a further sensor.
- 11. A method according to any preceding claim, wherein the components of the "activity quality index" (AQI) are defined by n=12 and the twelve parameters, P_i, are respectively time in bed, sleep end time, actual sleep time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time and wake movement RMS.
- 12. A method according to claim 11, wherein the constant C is 52.42 and the constants C_i associated with each of the parameters P_i respectively are -1.887,

0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112 and 0.001238.

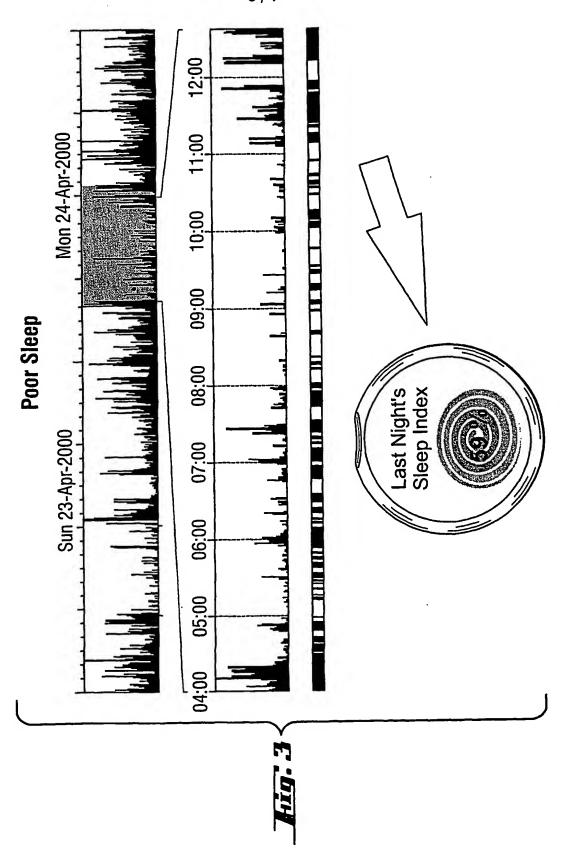
- 13. A computer readable storage medium comprising instructions for performing the steps of a method in accordance with any of the preceding claims.
- 14. A computer configured to perform the steps of a method in accordance with any of the preceding claims.



2/7

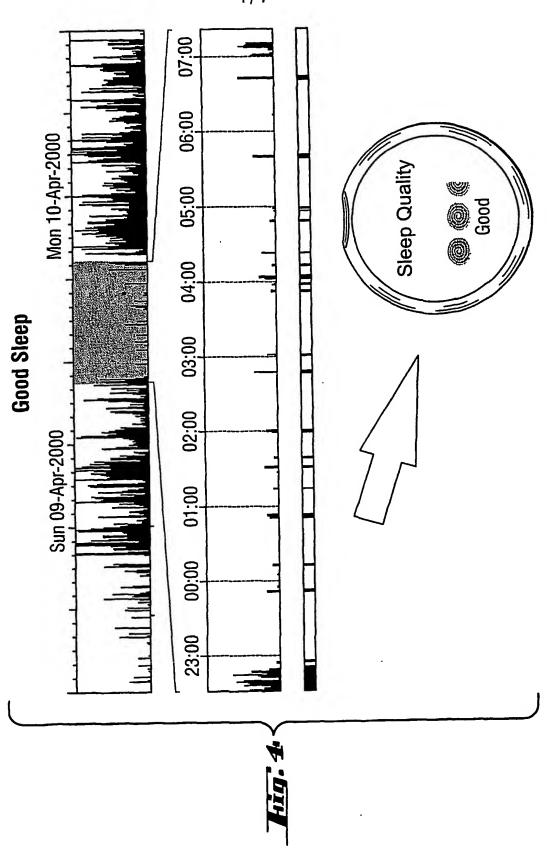


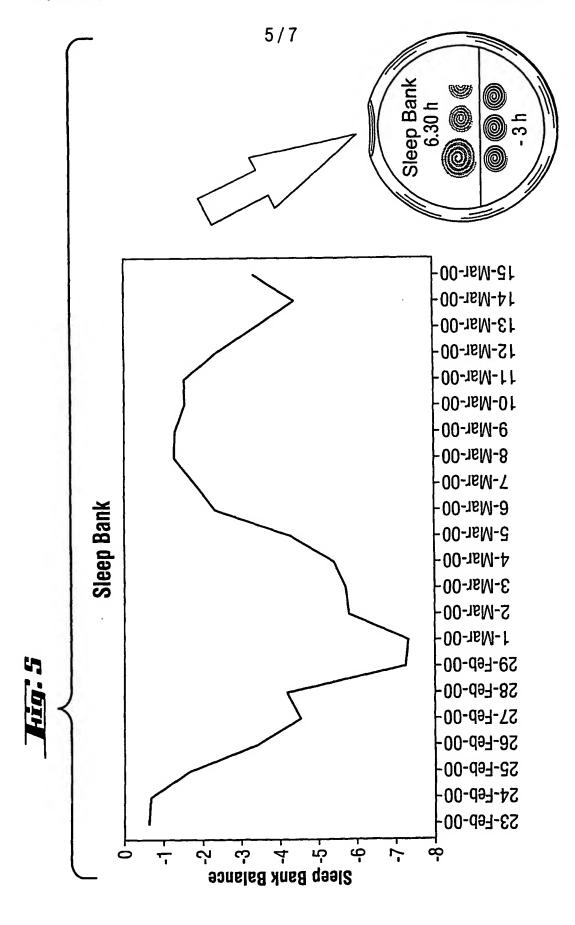
Hig. 2

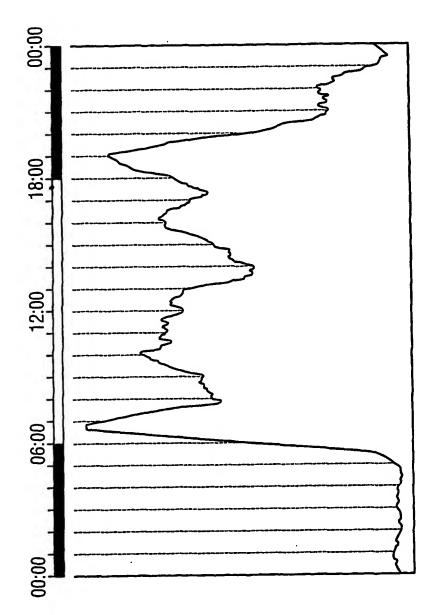


PCT/US01/19055

4/7

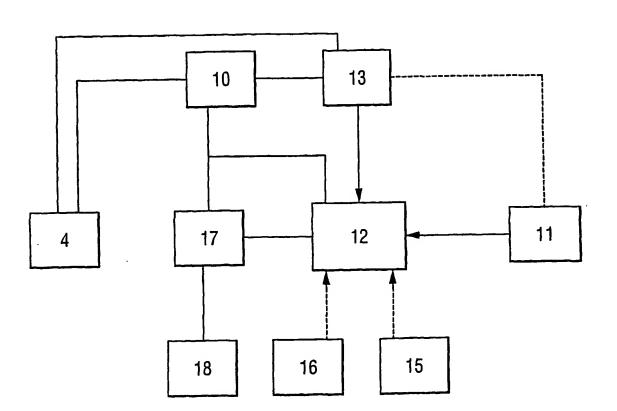








Jig: 7



INTERNATIONAL SEARCH REPORT

ional Application No PCT/US 01/19055

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B5/113 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC $\,\,^7$ $\,\,$ A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, BIOSIS

C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 679 453 A (UNIV RENNES) 29 January 1993 (1993-01-29)	1-3,7,8
Α	page 7, line 10 -page 14, line 4; tables 1,2	4-6,9,10
Y	FR 2 727 850 A (ELA MEDICAL SA) 14 June 1996 (1996-06-14) page 10, line 3 - line 24 page 8, line 11 - line 18 page 6, line 14 - line 19; table 1	1-3,7,8
A	EP 0 970 655 A (CARPE DIEM COMERCIAL SANITARIA) 12 January 2000 (2000-01-12) column 32, line 5 - line 29 column 31, line 35 - line 57	1

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents: 'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the International filing date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'O' document referring to an oral disclosure, use, exhibition or other means 'P' document published prior to the international filing date but later than the priority date claimed	 "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the Invention "X" document of particular relevance; the claimed Invention cannot be considered novel or cannot be considered to Involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed Invention cannot be considered to Involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2001	28/08/2001
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3018	Weihs, J

4

INTERNATIONAL SEARCH REPORT

Int Ional Application No PCT/US 01/19055

	PC1/US 01/19055
Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
US 5 719 825 A (DOTTER JAMES E) 17 February 1998 (1998-02-17) column 1, line 28 - line 51; tables 1,2	1,3,4,7,
DE 196 42 316 A (KRISCHENOWSKI DIRK) 23 April 1998 (1998-04-23) column 3, line 6 - line 33	1-3,8
COlumn 3, line 6 - line 33 BUYSSE D J ET AL: "THE PITTSBURGH SLEEP QUALITY INDEX A NEW INSTRUMENT FOR PSYCHIATRIC PRACTICE AND RESEARCH" PSYCHIATRY RESEARCH, vol. 28, no. 2, 1989, pages 193-214, XP001020700 ISSN: 0165-1781 abstract page 193	
	US 5 719 825 A (DOTTER JAMES E) 17 February 1998 (1998-02-17) column 1, line 28 - line 51; tables 1,2 DE 196 42 316 A (KRISCHENOWSKI DIRK) 23 April 1998 (1998-04-23) column 3, line 6 - line 33 BUYSSE D J ET AL: "THE PITTSBURGH SLEEP QUALITY INDEX A NEW INSTRUMENT FOR PSYCHIATRIC PRACTICE AND RESEARCH" PSYCHIATRY RESEARCH, vol. 28, no. 2, 1989, pages 193-214, XP001020700 ISSN: 0165-1781 abstract

4

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int Ional Application No PCT/US 01/19055

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2679453	A	29~01-1993	DE 69223969 D EP 0597032 A WO 9302731 A	12-02-1998 18-05-1994 18-02-1993
FR 2727850	Α	14-06-1996	NONE	
EP 0970655	A	12-01-2000	ES 2124186 A AU 5561698 A BR 9807497 A CN 1244104 T WO 9831275 A	16-01-1999 07-08-1998 21-03-2000 09-02-2000 23-07-1998
US 5719825	Α	17-02-1998	US 5848027 A	08-12-1998
DE 19642316	Α	23-04-1998	NONE	